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APR 21 2005

PATENT  
Atty. Dkt. No. 016777-0454**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Indu J. ISAACS  
Title: GLP-2 FORMULATIONS  
Appl. No.: 09/750,022  
Filing Date: 12/29/2000  
Examiner: Chih Min Kam  
Art Unit: 1653

|  |
|--|
| <b>CERTIFICATE OF FACSIMILE TRANSMISSION</b><br>I hereby certify that this paper is being facsimile transmitted to the<br>United States Patent and Trademark Office, Alexandria, Virginia<br>on the date below.<br><br>MARIE J. LUCIER<br>(Printed Name)<br><br><i>Marie J. Lucier</i><br>(Signature)<br><br>April 21, 2005<br>(Date of Deposit) |
|--|

**STATEMENT OF SUBSTANCE OF INTERVIEW**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance to 37 C.F.R. § 1.560(b), submitted herewith is a record of the substance of the interview on March 23, 2005, between Examiner Chih Min Kam, regarding the above-captioned application. As it is being submitted within one month of the Interview Summary mailing date, it response is a timely.

During the telephone interview, Examiner Kam proffered, and the undersigned agreed to, the amendments contained in the Examiner Amendment.

Respectfully submitted,

Date

April 21, 2005

By

Michele M. Simkin

FOLEY & LARDNER LLP  
Customer Number: 22428  
Telephone: (202) 672-5538  
Facsimile: (202) 672-5399

Michele M. Simkin  
Attorney for Applicant  
Registration No. 34,717



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
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## NOTICE OF ALLOWANCE AND FEE(S) DUE

7590

04/04/2005

Stephen A. Bent  
FOLEY & LARDNER  
Washington Harbour  
3000 K Street, N.W., Suite 500  
Washington, DC 20007-5109

EXAMINER

KAM. CHIH MIN

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 04/04/2005

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/750,022      | 12/29/2000  | Indu J. Jasany       | 016777/0454         | 6419             |

TITLE OF INVENTION: GLP-2 FORMULATIONS

| APPLN. TYPE    | SMALL ENTITY | ISSUE FEE | PUBLICATION FEE | TOTAL FEE(S) DUE | DATE DUE   |
|----------------|--------------|-----------|-----------------|------------------|------------|
| nonprovisional | NO           | \$1400    | \$300           | \$1700           | 07/05/2005 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

## HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status: .....

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER:** Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.



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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.       | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------|------------------|
| 02/750,022  | 12/29/2000  | Indu J. Isacs        | 016777/0454               | 6419             |
| 7590  | 04/04/2005  |                      | EXAMINER<br>KAM, CHIH MIN |                  |
| Stephen A. Bent<br>FOLEY & LARDNER<br>Washington Harbour<br>3000 K Street, N.W., Suite 500<br>Washington, DC 20007-5109 |             |                      | ART UNIT<br>1653          |                  |
| DATE MAILED: 04/04/2005   |             |                      |                           |                  |

**Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**  
 (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571) 272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

|                               |                        |                     |  |
|-------------------------------|------------------------|---------------------|--|
| <b>Notice of Allowability</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                               | 09/750,022             | ISAACS, INDU J.     |  |
|                               | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                               | Chih-Min Kam           | 1653                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/04/05.
2. ☒ The allowed claim(s) is/are 1-51, 53-55 and 58-78.
3. ☒ The drawings filed on 29 December 2000 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

|  |  |
|--|--|
| <ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br/>Paper No./Mail Date _____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</li> <li>6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date <u>20050323</u></li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____</li> </ol> |
|--|--|

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Art Unit: 1653

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Michele Simkin on March 23, 2005.

**Examiner's Amendments to the Claims:**

Cancel claim 52.

Claim 59 has been amended as follows:

59. (Currently amended) The GLP-2 formulation of claim 21, wherein the GLP-2 receptor antagonist has either (1) an amino acid substitution selected from the group consisting of Asp<sup>15</sup>, Phe<sup>22</sup>, Thr<sup>29</sup>, Thr<sup>32</sup>, Asp<sup>33</sup>, and combinations thereof; or (2) an amino acid substitution of Ala at position 2 by an amino acid selected from the group consisting of Leu, Cys, Glu, Arg, Trp and PO<sub>3</sub>-Tyr, wherein the residue or position for the amino acid substitution is numbered according to a mammalian GLP-2.

The following is an Examiner's Statement of Reasons for Allowance: The following references appear to be the closest art to the claimed invention. Knudsen *et al.* (WO 99/43361) teach a pharmaceutical composition comprising a GLP-2 derivative or analog, an isotonic agent such as mannitol, a buffer of histidine or sodium phosphate, a pharmaceutical acceptable carrier, a preservative and a surfactant; Kornfelt *et al.* (U. S. Patent 5,652,216) disclose using stabilizing amount of a pharmaceutically acceptable ampholyte such as glycine, histidine or GlyGly in a pharmaceutical preparation comprising glucagons. However, Knudsen *et al.* either alone or in combination with Kornfelt *et al.* do not teach or suggest a GLP-2 formulation comprising a medically useful amount of GLP2 or an analog thereof, a phosphate buffer, L-histidine for stabilizing the formulation and a bulking agent of mannitol and sucrose. Buhl *et al.* (J. Biol. Chem. 263, 8621-8624 (1988)) teach amino acid sequences of GLP-2 from different species; and Lund *et al.* (J. Biol. Chem. 258, 3280-3284 (1983)) teach nucleotide and corresponding deduced amino acid sequences of cDNA encoding two anglerfish pre-proglucagons, where the GLP-2 sequence in the angler fish pre-proglucagon is different from the mammalian GLP-2. Therefore, the claims are allowable over the art of record.

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Art Unit: 1653

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

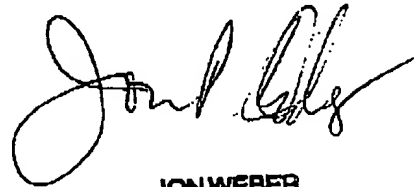
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Patent Examiner

CMK

CMK

March 23, 2005



JON WEBER  
SUPERVISORY PATENT EXAMINER

|                          |                        |  |                     |  |
|--------------------------|------------------------|--|---------------------|--|
| <b>Interview Summary</b> | <b>Application No.</b> |  | <b>Applicant(s)</b> |  |
|                          | 09/750,022             |  | ISAACS, INDU J.     |  |
|                          | <b>Examiner</b>        |  | <b>Art Unit</b>     |  |
|                          | Chih-Min Kam           |  | 1653                |  |

All participants (applicant, applicant's representative, PTO personnel):

(1) Chih-Min Kam. (3) \_\_\_\_\_

(2) Michele Simkin. (4) \_\_\_\_\_

Date of Interview: 23 March 2005.

Type: a) ☒ Telephonic b) ☐ Video Conference  
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☐ No.  
If Yes, brief description: \_\_\_\_\_

Claim(s) discussed: 52 and 59.

Identification of prior art discussed: \_\_\_\_\_

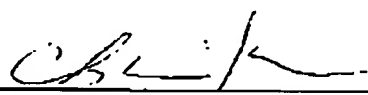
Agreement with respect to the claims f) ☒ was reached. g) ☐ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: To cancel claim 52 and amend claim 59 as indicated in the Examiner's Amendment.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

  
Examiner's signature, if required

U.S. Patent and Trademark Office

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

#### Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135, (35 U.S.C. 132).

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiner's Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

#### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.



|                                   |                                       |   |             |
|-----------------------------------|---------------------------------------|---|-------------|
| <b>Notice of References Cited</b> | Application/Control No.<br>09/750,022 | Applicant(s)/Patent Under<br>Reexamination<br>ISAACS, INDU J. |             |
|                                   | Examiner<br>Chih-Min Kam              | Art Unit<br>1653  | Page 1 of 1 |

## U.S. PATENT DOCUMENTS

| * |   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY | Name | Classification |
|---|---|--|-----------------|------|----------------|
|   | A | US-  |                 |      |                |
|   | B | US-  |                 |      |                |
|   | C | US-  |                 |      |                |
|   | D | US-  |                 |      |                |
|   | E | US-  |                 |      |                |
|   | F | US-  |                 |      |                |
|   | G | US-  |                 |      |                |
|   | H | US-  |                 |      |                |
|   | I | US-  |                 |      |                |
|   | J | US-  |                 |      |                |
|   | K | US-  |                 |      |                |
|   | L | US-  |                 |      |                |
|   | M | US-  |                 |      |                |

## FOREIGN PATENT DOCUMENTS

| * |   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY | Country | Name | Classification |
|---|---|--|-----------------|---------|------|----------------|
|   | N |  |                 |         |      |                |
|   | O |  |                 |         |      |                |
|   | P |  |                 |         |      |                |
|   | Q |  |                 |         |      |                |
|   | R |  |                 |         |      |                |
|   | S |  |                 |         |      |                |
|   | T |  |                 |         |      |                |

## NON-PATENT DOCUMENTS

| * |   | Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)   |
|---|---|---|
|   | U | Buhl et al., Naturally Occurring Products of Proglucagon 111-160 in the Porcine and Human Small Intestine, J. Biol. Chem. 263, 8621-8624 (1988).      |
|   | V | Lund et al., Anglerfish Islet Pre-proglucagon II, Nucleotide and corresponding amino acid Sequence of the cDNA, J. Biol. Chem. 258, 3280-3284 (1983). |
|   | W |   |
|   | X |   |

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

U.S. Patent and Trademark Office  
PTO-892 (Rev. 01-2001)

Notice of References Cited

Part of Paper No. 20050323